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PCT/KR2005/000120

PATENT COOPERATION TREATY

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
ROH, Jae-Chull

6F.,Seil Building, #727-13 Yeoksam-dong, Gangnam-gu
Seoul 135-080 Republic of Korea

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**16 MARCH 2005 (16.03.2005)**
Applicant's or agent's file reference WR04091CKP	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2005/000120	**14 JANUARY 2005 (14.01.2005)**	16 JANUARY 2004 (16.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 31/4422, A61P 9/00, A61K 9/14

Applicant

CHONG KUN DANG PHARMACEUTICAL CORP. et al

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [x] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
LEE, Mi Jeong
Telephone No. 82-42-481-5601

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2005/000120

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material
   - ☐ a sequence listing
   - ☐ table(s) related to the sequence listing

   b. format of material
   - ☐ in wirtten format
   - ☐ in computer readable form

   c. time of filing/furnishing
   - ☐ contained in the international application as filed.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 11	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1 - 11	NO
Industrial applicability (IA)	Claims	1 - 11	YES
	Claims		NO

2. Citations and explanations :

The following documents are referred to in this report:

D1: US 2004/0001886 A1 (01. Jan. 2004)
D2: Int. J. Pharmaceut. Vol.265, pp.125-132 (2003)
D3: US 2003/0091643 A1 (15 May 2003)

1. Novelty

Claims 1-9 of the present invention relate to amlodipine maleate granules coated with polymers such as polyvinylpyrrolidone, cellulose derivatives, and cyclodextrins, or sugars such as sucrose, sorbitol, and mannitol.

Claims 10, 11 of the present invention relate to a process for preparing the said amlodipine granules by fluidized-bed coating method.

D1 discloses granules comprising amlodipine, microcrystalline cellulose, polyvinylpyrrolidone to be compressed into tablets.

D2 discloses that amlodipine-cyclodextrin inclusion complex can increase photostability of amlodipine.

D3 discloses pharmaceutical compositions comprising dispersions of an acid-sensitive drug such as amlodipine and a neutral dispersion polymer such as cellulose derivatives and polyvinylalcohols with increased chemical stability.

The amlodipine compositions in D1-D3 and claims 1-9 of the present invention comprise amlodipine and the excipients in common, but the amlodipine compositions in claims 1-9 of the present invention differ from D1-D3 in that the amlodipine granules are coated with excipients rather than blended with them. The fluidized-bed coating method for amlodipine in claims 10, 11 of the present invention is not disclosed in any of D1-D3.

Therefore, claims 1-11 of the present invention are considered to be novel over D1-D3 [Article 33(2) PCT].

(Continued on the Supplemental Sheet.)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of :

Box V.

2. Inventive Step

Once it is known to combine amlodipine with certain excipients can increase the chemical stability of amlodipine maleate, it is very easy to a man skilled in the art to change the granulation methods, i.e. from blending amlodipine maleate with the excipients to coating amlodipine maleate with the excipients.
In addition, the fluidized-bed coating method is one of very general techniques in the art.
Therefore, the inventive step of claims 1-11 cannot be acknowledged over D1-D3 [Article 33(3) PCT].

3. Industrial Applicability

The subject-matter of claims 1-11 appears to be industrially applicable [Article 33(4) PCT].

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The brand names of "OPADRY-AMB", "OPADRY-OYC-7000A" are used as coating materials in the examples of the description. Even if the brand names are very familiar to a man skilled in the art, they still make the composition of the coating materials unclear.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 11	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1 - 11	NO
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